

UNITED STATES DISTRICT COURT  
DISTRICT OF MASSACHUSETTS

MICHELE ERKAN, on behalf of herself, )  
her minor child, and all others )  
similarly situated, )

Plaintiff, ) Civil Action  
vs. ) No. 12-12052-FDS  
)

NEW ENGLAND COMPOUNDING )  
PHARMACY, INC., d/b/a NEW ENGLAND )  
COMPOUNDING CENTER, et al., )  
Defendants. )

ROBERT COLE, )  
on behalf of himself and all )  
others similarly situated, )  
Plaintiffs )

vs. ) Civil Action  
No. 12-12066-FDS  
)

NEW ENGLAND COMPOUNDING )  
PHARMACY, INC., d/b/a NEW ENGLAND )  
COMPOUNDING CENTER, et al., )  
Defendants. )

BEFORE: THE HONORABLE F. DENNIS SAYLOR, IV

MOTION HEARING

John Joseph Moakley United States Courthouse  
Courtroom No. 2  
One Courthouse Way  
Boston, MA 02210

December 10, 2012  
11:30 a.m.

Valerie A. O'Hara  
Official Court Reporter  
John Joseph Moakley United States Courthouse  
One Courthouse Way, Room 3204  
Boston, MA 02210  
E-mail: vaohara@gmail.com

1 APPEARANCES:

2 For The Plaintiffs:

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Massachusetts 02142;

5 Robinson & Cole, LLP, KIMBERLY A. DOUGHERTY, ATTORNEY,  
6 One Boston Place, Suite 2500, Boston, Massachusetts 02108;

7 Sheff Law Offices, P.C., by FRANK J. FEDERICO, JR.,  
8 ESQ., Ten Tremont Street, Boston, Massachusetts 02108;

9 Ellis & Rapacki, by FREDRIC L. ELLIS, ESQ.,  
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10 Sugarman, Rogers, Barshak & Cohen, P.C., by Anthony V.  
11 Agudelo, Esq., 101 Merrimac Street, 9th Floor,  
Boston, Massachusetts 02114;

12 Law Offices of Mark Zamora and Associates, MARK ZAMORA,  
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13 Shapiro Haber & Urmy LLP, by APRIL KUEHNHOFF, 53 State  
14 Street, Boston, Massachusetts 02108;

15 For the Defendants:

16 Harris Beach PLLC, by, FREDERICK H. FERN, ESQ., 100 Wall  
Street, New York, New York 10005;

17 Hinshaw & Culbertson LLP, by GEOFFREY M. COAN, ESQ.,  
18 28 State Street, 24th Floor, Boston, Massachusetts 02109;

19 Tucker & Ellis LLP, by MATTHEW P. MORIARTY, ESQ.,  
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21 Tucker, Saltzman & Dyer, LLP, by SCOTT J. TUCKER, ESQ.,  
100 Franklin Street, Suite 801  
22 Boston, MA 02110;

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25 ATTORNEY, One Beacon Street, Boston, Massachusetts 02108;

1 APPEARANCES (CONTINUED):

2 For the Defendants:

3 Todd & Weld LLP, by HEIDI A. NADEL, ESQ.,  
4 28 State Street, 31st Floor, Boston, Massachusetts 02109;

5 For the United States:

6 United States Attorney's Office, by ZACHARY A. CUNHA,  
7 ASSISTANT UNITED STATES ATTORNEY, Suite 9200, 1 Courthouse Way,  
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9 VIA PHONE FOR The PLAINTIFFS:

10 Lieff, Cabraser, Heimann & Bernstein, LLP, by  
11 WENDY FLEISHMAN, ATTORNEY, 250 Hudson Street, 8th Floor,  
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1 PROCEEDINGS

2 THE CLERK: All rise. Thank you. Please be seated.  
3 Court is now in session. This is Civil Action 12-12052,  
4 Michelle Erkan vs. NECP, et al. and related cases. Counsel,  
5 please identify yourselves for the record.

6 MS. PARKER: Good morning, your Honor,  
7 Attorney Kristen Johnson Parker with Hagens, Berman for  
8 plaintiffs Erkan and Cole.

9 THE COURT: Good afternoon.

04:10PM 10 MS. DOUGHERTY: Good afternoon, your Honor,  
11 Kim Dougherty, Janet, Jenner & Suggs on behalf of Chad Green.

12 MR. ELLIS: Fredric Ellis for plaintiffs Cary and  
13 Schroder.

14 MR. FEDERICO: Frank Federico, Sheff Law Offices on  
15 behalf of the Martin plaintiffs, your Honor.

16 THE COURT: Okay.

17 MR. ZAMORA: Your Honor, Mark Zamora for Chad Green.

18 MR. AGUDELO: Anthony Agudelo from Sugarman, Rogers,  
19 Barshak & Cohen by for the plaintiff, Sandra Harrison.

04:10PM 20 THE COURT: Any other plaintiffs' counsel?

21 MS. KUEHNHOFF: Yes, sorry, pardon, April Kuehnhoff  
22 for Shapiro, Haber & Urmy on behalf of Tawan Jenkins and  
23 Franklin Jenkins.

24 THE COURT: Good afternoon, all.

25 MR. FERN: Good afternoon, your Honor, Frederick Fern

1 from Harris Beach on behalf of Defendant NECC, MSN and a number  
2 of the individual defendants, including Barry and Lisa Cadden  
3 and Greg and Carla Conigliaro.

4 MR. COAN: Good afternoon, your Honor, Geoff Coan,  
5 Mr. Fern's local counsel.

6 MR. MORIARTY: Good afternoon, your Honor,  
7 Matthew Moriarty on behalf of Ameridose.

8 MR. TUCKER: Good afternoon, your Honor, Scott Tucker,  
9 from Tucker, Heifetz & Saltzman with Mr. Moriarty.

04:11PM 10 THE COURT: Okay.

11 MS. NADEL: Good afternoon, your Honor, Heidi Nadel,  
12 co-counsel for Doug and Carla Conigliaro.

13 MS. SAMSON: Good afternoon, your Honor,  
14 Nicki Samson from Michaels, Ward & Rabinovitz, counsel for  
15 Medical Sales Management.

16 THE COURT: All right. Is anyone on the telephone?

17 MS. FLEISHMAN: Wendy Fleishman from Lieff, Cabraser  
18 on behalf of the plaintiff Raymond McDow and Roseanne Brooks,  
19 your Honor, good afternoon.

04:12PM 20 THE COURT: Good afternoon. All right. This is a  
21 status conference in this case. I'm going to ask counsel  
22 present in the courtroom to remain seated and to speak into the  
23 microphone so that people on the telephone can hear you. I  
24 have at least three or four, possibly more matters to take up  
25 in no particular order.

1 First, the issue of the preservation orders. I've  
2 reviewed the submissions by the parties. There's a pending  
3 motion for oral argument. I'm not sure that I need -- I'll  
4 grant it, but I'm not sure that I need to hear. I guess my  
5 inclination is to issue three orders more or less along the  
6 lines proposed by the defendants. I would issue an order for  
7 NECC, one for Ameridose and one for the individual defendants.

8 The principal issue, as I see it, is whether I should  
9 require NECC in some form or another to communicate with third  
04:13PM 10 parties and to request that they preserve evidence. I'm not  
11 inclined to approach the problem that way, although I do  
12 acknowledge, of course, that there may be evidence in the hands  
13 of third parties that in some form or another may need to be  
14 either obtained or preserved, and I'm also conscious, of  
15 course, that various governmental authorities may have seized  
16 or otherwise obtained evidence that is not in the custody or  
17 control of defendants, and whatever order I issue in that  
18 regard can only apply to that which is in their custody and  
19 control.

04:14PM 20 But did you want to be heard? I guess Mr. Fern, was  
21 it your motion?

22 MR. FERN: It's not, Judge. We're willing to stand on  
23 the papers. Obviously the Court has an inclination as to which  
24 way you want to rule, and we're willing to stand by what we  
25 submitted.

1           THE COURT: Like everything else I'm going to do in  
2 this case, you know, all of these orders are always subject to  
3 modification pending changed conditions, and certainly I will  
4 entertain anything that is reasonable and legal and within my  
5 jurisdiction. If it appears necessary to maintain the status  
6 quo before valuable evidence is lost --

7           MS. PARKER: Your Honor.

8           THE COURT: Ms. Parker.

9           MS. PARKER: If plaintiffs may just briefly be heard?

04:15PM 10          THE COURT: Yes.

11          MS. PARKER: There is one issue in the NECC  
12 preservation order that we believe may merit the Court's  
13 attention. Defendants have suggested language that requires  
14 them to preserve the clean rooms. It's a paragraph in the  
15 order that specifically deals with that. Plaintiffs had asked  
16 that that duty to preserve extend to the premises for the NECC  
17 facility, not simply the clean rooms, at least until the time  
18 that the plaintiff's inspection has occurred.

19          THE COURT: I guess that's segues into the next point.  
04:15PM 20 I saw that Judge Boal held a hearing. Where do matters stand  
21 on the inspection issue, Ms. Parker?

22          MS. PARKER: Yes. That's correct, your Honor,  
23 Judge Boal did issue an order recently. The plaintiffs have  
24 conferred among ourselves. We are in the process of putting  
25 together a protocol, and we intend to submit that to defendants

1 tomorrow, and we intend to move with all due haste here.

2 THE COURT: All right. Mr. Fern, where does the  
3 inspection issue stand from your perspective?

4 MR. FERN: Judge, I've been on the road all day.  
5 Magistrate Boal's decision, which was issued some time early  
6 this afternoon was just handed to me when I walked in.

7 THE COURT: Okay. I've been on the bench, so I  
8 haven't seen it either. Hum me a few bars here, what did she  
9 say?

04:16PM 10 MR. FERN: Judge, how about if I defer to someone  
11 who's read it?

12 THE COURT: Okay, I'll take that.

13 MS. DOUGHERTY: Your Honor, I'm happy to provide you  
14 some information with respect to the order. Judge Boal has  
15 issued an order which would allow four days of testing by the  
16 plaintiffs at the facility. Your Honor specifically on page 9  
17 also allowed destructive testing. We requested minimally  
18 destructive testing of "sampling of the wall, roof, ceiling and  
19 foundational assemblies and cavities, interior mechanical  
04:17PM 20 systems, including but not limited to HVAC systems and its duct  
21 work and plumbing systems, sampling of edging of carpeting and  
22 testing of the clean room."

23 Certainly, your Honor, because she has allowed us to  
24 do that type of sampling and found that sampling to be  
25 reasonable and not available through any other source, we



1 believe that it should be preserved until we've had the  
2 opportunity to do the sampling and the testing that we need.

3 The Judge -- Judge Boal also ordered for us to work  
4 with the U.S. Attorney's Office. We're happy to do that,  
5 provide notice. We have a proposal of a protocol that is due  
6 to Judge Boal by Friday, so if we don't have a joint protocol,  
7 we are to submit competing protocols. What we had indicated to  
8 Judge Boal at the hearing last week was that we would like to  
9 be in there on the 18th through the 21st.

04:18PM 10 I've conferred in advance of the hearing with  
11 U.S. Attorney Cunha who has indicated that he is working on  
12 that time frame to also accommodate and hope that we are able  
13 to get in there for those four days.

14 THE COURT: All right. That's the civil division of  
15 the U.S. Attorney's Office representing, what, the DEA or the  
16 FDA?

17 MR. CUNHA: Your Honor, if I might?

18 THE COURT: Oh, yes.

19 MR. CUNHA: Zachary Cunha on behalf of the  
04:18PM 20 United States.

21 THE COURT: Yes.

22 MR. CUNHA: I'm here only as an interested party, and,  
23 accordingly, wasn't otherwise going to participate. I am here  
24 on behalf of the civil division of the office. We are  
25 coordinating in connection with this litigation to ensure that

1 there are not any actions that would impinge on the ongoing  
2 investigation being conducted by the office.

3 To that end, I had indicated that we're happy to  
4 review any protocol and that to the extent that that protocol  
5 doesn't create problems for the ongoing investigation, we would  
6 try and expedite it as much as we can.

7 THE COURT: This is simply informative. I've referred  
8 this matter to Magistrate Judge Boal, as you know, and I asked  
9 the question because there are at least two other potential  
04:19PM 10 players here, if not more, the Commonwealth and the grand  
11 jury/criminal division of the U.S. Attorney's Office, and it's  
12 not clear to me exactly what needs to be coordinated or how,  
13 but I want to make sure that all interested parties have a say,  
14 again, because in my mind, at least, the public health comes  
15 first.

16 MR. CUNHA: Just to be clear, your Honor, although I  
17 sit in the civil division, I am here on behalf of the entirety  
18 of my office, and in response to Judge Boal's invitation, we  
19 forwarded her order to the state, so they are certainly aware  
04:20PM 20 of the issues and had the opportunity to weigh in if they were  
21 so inclined.

22 THE COURT: Okay. As to the narrow issue before me,  
23 whether the preservation order ought to address preservation of  
24 the premises for a period of what may be not much more than a  
25 week, I'll take that under advisement. It's a little more

1 complicated than preserving documents and computerized  
2 information, but I will take that under advisement.

3 Anything else on the preservation orders? Mr. Fern,  
4 you have a frown suggesting you have something you want to tell  
5 me?

6 MR. FERN: No, Judge, no frown. I was trying to make  
7 the Judge's job a little easier. We have no problem --

8 THE COURT: I'm always happy with that, but usually  
9 when people say that, I don't find my job is.

04:20PM 10 MR. FERN: Well, Judge, clearly my intention is to do  
11 that, and we have agreed and have represented in our papers and  
12 I represent now in open court that we will do our best to  
13 maintain the status quo on the premises between now and  
14 whatever date the discovery and inspection is held pursuant to  
15 Magistrate Judge Boal's directive.

16 My issue -- so, as to that point, that's fine.  
17 Magistrate Boal for the first time when we get there on  
18 Thursday, my partner, Ms. Curry was present, and we were told  
19 for the first time that plaintiffs wanted to do destructive  
04:21PM 20 testing on the premises, punch holes in the wall, take tiles  
21 off the roof, pull off paneling so they can see behind the  
22 walls to see whether there are rusty nails or shiny nails.

23 The premises is not owned by NECC. There is a  
24 landlord GDC Holdings, Inc. and GDC Property Management, Inc.  
25 who manage the premises who is not NECC. That is somewhat of a

1 taking of personal property. When this was raised for the  
2 first time, we were not aware of it. We did not raise it in  
3 our papers, and Magistrate Boal said there was no evidence  
4 before her to back up the assertion that NECC did not own the  
5 premises.

6 It was kind of a curve ball, your Honor, we are  
7 willing to submit within 48 hours a deed, a tax bill or  
8 something to show who the actual owner of the premises is and  
9 somehow limit the discovery and inspection to nondestructive  
04:22PM 10 testing so the premises aren't altered to the actual owner who  
11 is not a party to the action.

12 THE COURT: Here's what I'm going to do with that.  
13 I'm going to leave the issue of the inspection and testing with  
14 Magistrate Judge Boal. I referred the whole issue to her. If  
15 you need a modification or a protective order, you should move  
16 in her court in the first instance, and if you're not  
17 satisfied, I'll take up an objection even on an emergency  
18 basis. I'm around basically, you know, if you need emergency  
19 relief, I'll do my best to hear you, but I'm going to leave  
04:23PM 20 that ball in her court for the time being.

21 All right. In no particular order, I also have the  
22 issue --

23 MR. MORIARTY: Your Honor, I'm sorry, excuse me, it's  
24 Matt Moriarty for Ameridose. There is an issue in the proposed  
25 Ameridose preservation order, and I didn't know whether you had

1 just taken up the NECC one or all of them at the same time.

2 THE COURT: All of them, so go ahead.

3 MR. MORIARTY: Okay. The competing provisions are on  
4 page 3 of the proposal, has to do with the preservation of  
5 backups.

6 THE COURT: Yes.

7 MR. MORIARTY: So one thing is that they want backups  
8 going back in time without any sort of limitation in their  
9 submission, they just say prior to January 1st, 2013, which is  
04:24PM 10 not easy because backups are frequently overwritten, et cetera,  
11 so they know, and we've already discussed whether, you know, if  
12 those are not available, obviously that's not a problem, but I  
13 think the bigger issue for right now is that once the  
14 litigation started, our client and its vendor went in and did  
15 backups and started the computer forensic work immediately,  
16 which is back in October.

17 The plaintiffs, at least as I understand it, want  
18 backups subsequent to the October 14th, 2012 preservation,  
19 which means that we would have to go back in and do this again  
04:24PM 20 once or more times because they want any backups done between  
21 October 14th, 2012 and the end of this calendar year.

22 I will allow the plaintiffs to set forth their reasons  
23 for wanting that, but we object to having to go and do these  
24 things again or again and again just to retrieve backups.

25 THE COURT: Who wants to take that up, Ms. Parker?

1 MS. PARKER: I'll address that, thank you. Our  
2 thought here was not to ask Mr. Moriarty or his client to do  
3 anything again, rather that there's a period of time after --  
4 let me start over.

5 Ameridose has represented that in October when the  
6 problems with NECC's products came to light, they did a full  
7 set of imaging of their systems, which I understand to include  
8 copies of hard drives and the like. We're not asking them to  
9 do that again, at least not at this point in time, we have no  
04:25PM 10 grounds for doing so and would not so impose.

11 What we are asking is that to the extent that backup  
12 material currently exists that postdates those October samples  
13 that we've been -- the images that we've been informed of, we  
14 would ask that they retain, not duplicate or produce, but at  
15 this time retain those backup materials and not overwrite those  
16 until January 1st, therefore, moving forward January 1st and  
17 after they would be free to do so.

18 THE COURT: One of my privileges, of course, as a  
19 District Judge is these issues are usually dealt with by the  
04:26PM 20 magistrate judges, and I don't have to get into the details.

21 MS. PARKER: Yes, your Honor.

22 THE COURT: But, you know, in the old days, ancient  
23 history, things would be backed up on tapes, and the tapes  
24 would be recycled every week or so, so simply to preserve it  
25 was this incredible problem because you were always overriding

1 an old tape.

2 I don't know what the modern version of that is, but  
3 my guess is it's not for you to say that they can't destroy any  
4 current backup may mean that they need to change their way of  
5 doing business every day and preserve something every day  
6 because otherwise something is overwritten. Mr. Moriarty, do  
7 you know the answer to this?

8 MR. MORIARTY: I do not know the answer to your  
9 specific question, but, historically, they have overwritten, I  
04:27PM 10 know that.

11 MS. PARKER: I believe I actually know the answer from  
12 speaking with Mr. Moriarty's colleague. I understand that it  
13 is not the case on a daily basis backups are made. We are not  
14 asking them to do anything or to stop the process moving  
15 forward from January 1 but simply to the extent that copies  
16 other than those in October exist that they save those.

17 The specifics that I understand here as opposed to  
18 tapes, your Honor, periodically copies of hard drives or the  
19 systems will be saved to a third-party vendor's system as a  
04:27PM 20 form of backing it up.

21 THE COURT: All right.

22 MS. PARKER: So to the extent that there are images  
23 from other dates and other time periods that currently exist  
24 there, we would ask that they not be allowed to rewrite those  
25 until after January 1st.

1 THE COURT: Again, that's a problem, let's say they do  
2 that once a week and let's say it's the electronic or cloud  
3 version of a tape, in other words, let's say every Sunday night  
4 they take a snapshot of the system and it overwrites, you know,  
5 the last snapshot, and then they do it again and they do it  
6 again, and they're just simply backing it up that way, to stop  
7 that process in its tracks is not going to be quite as simple  
8 as what you suggested.

9 Isn't effectively what they would have to do, what  
04:28PM 10 they did on October 14th, in other words, take a picture of the  
11 entire system as it existed as of that moment?

12 MS. PARKER: No, your Honor, that's not what we're  
13 intending to ask for. So let me see if I can clarify, rather  
14 to the extent they have copies from earlier dates or later  
15 dates that already exist that have already been taken in the  
16 course of things, we'd ask them to preserve a copy.

17 Now, I understand from speaking with Mr. Moriarty's  
18 colleague that there is no set, for example, daily or weekly  
19 backup, that it sort of happens incrementally. Our thought for  
04:28PM 20 asking for a backup after October is that plaintiffs would in  
21 theory, and, again, we're not asking for this to be produced  
22 now, be entitled to correspondence among Ameridose employees  
23 about how they're dealing with and responding to this issue.

24 So that's the content that we're hoping to preserve.  
25 We thought that asking until January 1st was an appropriate



1 reasonable time period but, if, for example, your Honor wanted  
2 to say as of today, we would, you know, certainly consider that  
3 as well. The idea was to go slightly beyond that October image  
4 to the extent that it already existed.

5 THE COURT: Mr. Moriarty.

6 MR. MORIARTY: I don't think I need to add anything  
7 further.

8 THE COURT: All right. Here's what I'd like you to  
9 do. On this issue only, I'd like you to confer one more time  
04:29PM 10 and see if you can't agree on language or narrow it further.  
11 I'm very hesitant to do this on my own for fear that I will do  
12 something that will create a greater problem than whatever it  
13 is I'm trying to solve, but if you think it's not intrusive,  
14 Ms. Parker, see if you can't convince Ameridose that that's  
15 true, and maybe you can agree on language, and if it is  
16 intrusive, then just give me the two competing considerations,  
17 and I'll do that.

18 I think in the meantime what I may do is simply issue  
19 orders and then amend them later to include this additional  
04:30PM 20 language depending on the timing you submit additional  
21 language.

22 MS. PARKER: Certainly, your Honor, and I'm confident  
23 that we can work out something.

24 THE COURT: All right. That's the preservation orders  
25 then. Let me take up the issue of interim liaison counsel.

1 Just to be clear again, this is not lead counsel, which is a  
2 decision that will await another day depending on where the  
3 JPML decides to assign the cases. It's not even liaison  
4 counsel, it's interim liaison counsel in order to try to  
5 facilitate the next two or three or whatever it is months until  
6 we have the JPML decision.

7 Some of these requirements or suggestions predate  
8 electronic filing. Again, in the old days, it was important  
9 when there was paper to distribute to have one principal  
04:31PM 10 contact for distributing paper, and it's not clear to me in the  
11 electronic age whether that's a particularly important  
12 function.

13 I suppose there may be paper to distribute at some  
14 point, or if, you know, paper service is made or required, we  
15 may need a liaison counsel, but as I see the principal purpose  
16 in the interim is to have a single point of contact for  
17 opposing counsel so that, for example, when there's a meet and  
18 confer obligation, Mr. Fern's office, for example, will have  
19 one person to contact on the plaintiff's side instead of trying  
04:31PM 20 to contact all plaintiffs' counsel and dido for the individual  
21 defendants.

22 So I'm going to issue an order setting out these  
23 relatively minimal duties, and I will appoint interim liaison  
24 counsel again for those purposes. It is very much not intended  
25 to place a thumb on the scale ultimately for who will be lead

1 counsel. That is an issue that will again await another day,  
2 but, again, for this limited purpose and for this short period  
3 of time, I am going to appoint Ms. Parker as plaintiffs'  
4 interim liaison counsel.

5 Ms. Dougherty submitted an application, and I think it  
6 will work best in the short term without two candidates,  
7 although I certainly welcome and encourage whatever  
8 Ms. Dougherty wants to contribute to help facilitate  
9 communications, and for the individual defendants, I'll appoint  
04:32PM 10 Ms. Nadel from Todd & Weld as liaison counsel. I don't know  
11 that I need to appoint counsel for NECC, Ameridose are  
12 represented by one law firm, and I assume Mr. Fern and  
13 Mr. Moriarty are taking on the lead.

14 So, again, just to reiterate to the extent that there  
15 is paper of some sort that needs to be distributed, and perhaps  
16 as automatic discovery proceeds, such things will occur, it  
17 will be the obligation of liaison counsel to maintain  
18 up-to-date service lists and to distribute paper, otherwise the  
19 principal purpose will be to be the point of contact whenever  
04:33PM 20 contact is necessary, particularly as to any meet and confer  
21 obligation involving all counsel, and I'll issue written orders  
22 that cover this issue. Any questions or issues in that regard?  
23 Okay.

24 I have pending two or possibly four motions for  
25 remand. I have read the papers in at least some of the

1 underlying cases. I think it would be helpful in the Cary and  
2 Schroder cases, which are ripe for resolution, to hear from the  
3 defense. Who wants to take the lead on this as to why I should  
4 not remand these cases, or do you want to just rest on the  
5 papers? Mr. Fern.

6 MR. FERN: Judge, I think our position was set forth a  
7 couple weeks ago. At the last conference your Honor said that  
8 he was going to rule on the papers, and to be blunt, I was not  
9 prepared to orally argue because I know when one of the  
04:35PM 10 plaintiffs stood up the last time and said that oral argument  
11 was not necessary, so I took that to mean the Judge was going  
12 to rule on the papers.

13 THE COURT: I'm certainly prepared to do that. I  
14 guess I am giving you an opportunity. I am looking carefully  
15 at the cases. It's a little more complicated than it used to  
16 be. I mean, the rule used to be simply it was a well-pleaded  
17 complaint rule, and if you didn't state a federal claim that  
18 was that. It's a bit more complicated around the edges now,  
19 and one of the areas where it's complicated is in matters  
04:35PM 20 involving pharmaceuticals and the FDA, and I'm looking  
21 carefully at it, but some of the arguments, you know, for  
22 example, as to inefficiency of having parallel state and  
23 federal litigation, while no doubt they're true, it's not  
24 really a basis for me to make a subject matter jurisdiction  
25 issue.

1           Either there is federal question jurisdiction or there  
2           is not, and if there is not, then it becomes an issue of  
3           diversity, and whether an in-state defendant has removed the  
4           case, which it is not jurisdictional, but the statute doesn't  
5           provide for removal in those circumstances. Mr. Moriarty, do  
6           you want to be heard on this issue, or are you prepared to rest  
7           on the papers as well?

8           MR. MORIARTY: Well, your Honor, I think to some  
9           degree I'm in the same boat as Mr. Fern, but if your Honor has  
04:36PM 10          specific questions because we may know a little bit more about  
11          the documents or the way these claims tend to go because we've  
12          been through this on these specific sort of cases before  
13          involving federal regulations, I'm happy to answer any  
14          questions that you have about that regarding Ameridose, but one  
15          of the key distinctions between Ameridose and NECC is this  
16          whole legal issue regarding the regulation of compounding  
17          pharmacies, which as I understand is a huge part of their  
18          separate papers.

19          Ameridose doesn't necessarily have that same problem  
04:37PM 20          because it not only had licenses as a compounding pharmacy but  
21          also licenses or permission to manufacture from FDA, but I'm  
22          happy to answer any questions you have about documents or  
23          evidentiary issues or why we think this is a federal question.

24          THE COURT: Well, I guess I'll, you know, if you want  
25          to take it up, I'll give you the opportunity. My basic

1 question is what is the federal issue, what is the federal  
2 question? There are cases out there, for example, where, you  
3 know, the FDA mandates that a label contain certain language  
4 and then a state law claim for failure to warn based on the  
5 inadequacy of the labeling, at least as I might in my limited  
6 understanding of the law there's cases out there that says,  
7 well, you can't answer that question without interpreting  
8 federal law, and so it presents a federal question.

9 What is the federal question here? How is the  
04:38PM 10 pharmacy compounding issue here at play in the plaintiff's  
11 cause of action for negligence, breach of warranty, et cetera?  
12 Does anyone want to take that up?

13 MR. MORIARTY: Do you want to discuss that first as  
14 far as NECC is concerned?

15 THE COURT: Again, you don't need to, I'm just giving  
16 you the opportunity.

17 MR. MORIARTY: At least as far as Ameridose is  
18 concerned, generally what these plaintiffs tried to do is take  
19 federal regulatory schemes such as the general good  
04:38PM 20 manufacturing practices, which is part of the United States  
21 Code, and then the actual provisions of it have been deferred  
22 to FDA to write regs., so we have a regulatory scheme for not  
23 only that but the regulatory scheme refers to the United States  
24 Pharmacopeia, which is sort of the official, I mean, it's  
25 adopted under the Code of Federal Regulations.

1           So when the plaintiffs start to talk about how drugs  
2     are manufactured and the meaning of current and good general  
3     manufacturing or the United States Pharmacopeia, it  
4     automatically implicates federal issues regarding what those  
5     regulatory schemes mean and what the standard of care, for lack  
6     of a better term, is regarding the manufacturing of  
7     pharmaceutical, and it really doesn't matter quite frankly  
8     whether it's a compounded product so far as Ameridose is  
9     concerned, it may make a difference as far as NECC is  
04:39PM 10    concerned, but whether it's compounded or manufactured, you're  
11    still supposed to comply with these, and so they immediately  
12    get into issues regarding the applicable law, the applicable  
13    regulations, the applicable standard of care, what they mean  
14    and things of that nature.

15           Then you get into the next layer, which is more of an  
16    evidentiary layer of, okay, what does a 483 mean, what does a  
17    warning letter mean when they're issued by the FDA so far as  
18    the legal effect of them and the evidentiary effect of them.  
19    Do they constitute some sort of a finding that the  
04:40PM 20    manufacturing facility was in noncompliance, and, if so, what  
21    does that mean, or does it mean something completely different?

22           So as far as Ameridose is concerned, that's part of  
23    the issue of why this is a federal question, and the federal  
24    courts are uniquely in a position to analyze those issues, for  
25    example, in the case of Dick vs. American Home, it goes through

1 page after page of why the plaintiff couldn't prove their case  
2 just based on alleging violations of CGMPs and the existence of  
3 warning letters or 483s, and the federal court was able to  
4 dissect those out and was in a unique position to know what all  
5 of that meant.

6 THE COURT: All right. Does counsel in the Cary or  
7 Schroder case wish to respond?

8 MR. ELLIS: Well, just briefly, your Honor --

9 THE COURT: Mr. Ellis?

04:41PM 10 MR. ELLIS: Yes, Fredric Ellis. I think the problem  
11 with their argument and their whole brief is how he prefaced  
12 his argument just right now, "Generally what these plaintiffs  
13 try to do." Well, the real issue is what did we do in our  
14 complaints? And we never mentioned anything about federal law,  
15 federal agencies, the FDA, nothing, and there's just no federal  
16 question that is raised by our complaint, period, and so their  
17 whole brief is, well, they could allege this, other plaintiffs  
18 have alleged this, but we don't, so we think that ends the  
19 issue.

04:42PM 20 And the U.S.P., it's a private nongovernmental entity  
21 that basically sets testing standards. That has nothing to do  
22 with the government, and we didn't move to file a reply brief  
23 to their brief because their arguments that they raise in their  
24 brief, they're just no stronger than they were in their notice  
25 of removal. For instance, they argue that we allege that there



1 was contamination present at the site, that NECC's own  
2 environmental monitoring revealed that, and they failed to take  
3 any action to stop it.

4 So they allege what? We've raised the federal issue.  
5 Why? Well, that's what the FDA said in their 483. Well, that  
6 doesn't make it a federal issue, it's a fact, we allege that as  
7 a fact. They failed to remedy the environmental contamination  
8 that they knew of. That's negligence, that's gross negligence,  
9 but it's not a federal issue, so, you know, in our view, you  
04:43PM 10 look at our complaints, you will not see the word "federal,"  
11 you will not see anything about 483s, you'll not see warning  
12 letters, you will not see anything.

13 All you see is a garden variety state tort causes of  
14 action, wrongful death, negligence, breach of warranty, and,  
15 you know, in our view this one is absolutely clear, I mean, you  
16 know maybe other cases may stand on different footings, maybe  
17 they allege something in their complaints that could raise a  
18 federal issue, but I think if you look at our complaints,  
19 there's nothing there, Judge, and as to diversity, it's  
04:44PM 20 absolutely clear, you can't remove, they're an in-state  
21 defendant, they can't remove, period.

22 THE COURT: My understanding of the statute is that  
23 it's not jurisdictional in the sense that it can be waived, but  
24 the statute says you can't remove, and --

25 MR. ELLIS: That's correct.

1 THE COURT: -- so if it hasn't been waived, I think if  
2 it is a question of diversity, remand is required. The only  
3 question is whether there's a federal question raised.

4 MR. ELLIS: Right.

5 THE COURT: All right. I'm going to -- I have the  
6 motions under advisement, and I will again resolve that as  
7 quickly as I can. I understand that a couple more motions to  
8 remand have been filed in two other cases, which I have not had  
9 a chance to look at, but I will take those up in due course as  
04:45PM 10 well.

11 MR. ELLIS: Judge, could I say one more thing?

12 THE COURT: Yes.

13 MR. ELLIS: At the last hearing, I heard you express  
14 some concern about if cases get remanded to state court that  
15 we'll have another track of discovery and litigation. If these  
16 cases are remanded, I can assure you we will work closely with  
17 the counsel in the MDL, I already have a pretty good  
18 relationship with Ms. Dougherty.

19 THE COURT: I think, I hope -- I can't remember what I  
04:45PM 20 said, frankly. I'm hoping that there will be a special -- if  
21 there are a lot of them, they will be especially assigned to  
22 one Judge at the Superior Court so that that Judge and I can  
23 coordinate among other things and make sure that we're not  
24 working at cross purposes. There are bound to be some bumps in  
25 the road between now and then assuming that that's how it plays

1 out.

2 MR. ELLIS: We will also try to achieve whatever  
3 efficiencies we can achieve on the state level, and also,  
4 Judge, I've been involved in several MDLs, and if you want  
5 state liaison counsel, some type of liaison between the state  
6 litigation and federal, I'd be more than willing to serve.

7 THE COURT: I understand. This is frankly --

8 MR. ELLIS: Premature.

9 THE COURT: -- routine. Well, it's premature, but  
04:46PM 10 it's also routine to have separate tracks for state and federal  
11 cases.

12 MR. ELLIS: Exactly.

13 THE COURT: Well, I think I've said what I need to  
14 say. It's under advisement, and I expect to issue a prompt  
15 ruling. What else do we have to talk about? I would like to  
16 see counsel with some regularity in the short term, but it's  
17 not clear to me that we need to meet unless there's an  
18 emergency issue until after the first of the year, but I'll  
19 hear counsel on that subject or any other subject people want  
04:47PM 20 to take up while I have you here. Ms. Parker.

21 MS. PARKER: Yes, your Honor. From the plaintiff's  
22 perspective, aside from the issue of the inspection, we see no  
23 need that defense counsel should have to travel to Boston  
24 between now and the first of the year. Obviously we do think  
25 that the inspection should go forward with all due haste.

1 We've suggested the 18th to the 21st. I understand you've left  
2 that to the magistrate. Defendants seem amenable to that,  
3 although I won't hold them to it.

4 THE COURT: Again, subject to the statutory procedure  
5 for objections or appeals or whatever we call it, which I can  
6 take up on emergency basis, if required.

7 MS. PARKER: Certainly. Thank you, your Honor.

8 THE COURT: Mr. Fern.

9 MR. FERN: Nothing further, Judge. We have spoken  
04:47PM 10 among the plaintiffs and myself and Mr. Moriarty in an attempt  
11 to catch a break, spend some time with our families over the  
12 holidays. If we can come back after the first of the year, I  
13 think everybody would be amenable, and no one is in a rush to  
14 come back to the courtroom. I'm sure we'll have plenty of time  
15 here before you on this case, your Honor.

16 THE COURT: Again, I do permit telephone conferences.  
17 You shouldn't feel the need to come up here for every one of  
18 these things. You also should know if you don't, I have issued  
19 a standing order encouraging the appearance of junior or  
04:48PM 20 relatively inexperienced counsel. A lot of Judges insist on  
21 having the senior most counsel present for all purposes. I  
22 don't require that at all, and, in fact, I encourage the  
23 opposite because it's often the case that the more junior  
24 person who may have drafted a motion and may understand the  
25 facts in the case a lot better, understands the issues better,

1 and certainly from a cost-containment perspective, it's usually  
2 preferable to have the more junior person.

3 I'll leave it up to you all obviously to send who you  
4 want to send and argue who you want to argue, have argue, but  
5 just so you understand, I do permit that. Mr. Moriarty,  
6 anything further you want to take up?

7 MR. MORIARTY: No, your Honor, I'll be back in  
8 Cleveland on the 3rd, and I'd be happy to come to Boston any  
9 time on or after the 5th of January.

04:49PM 10 THE COURT: Ms. Nadel.

11 MR. NADEL: Nothing, your Honor. Thank you.

12 THE COURT: Anything else anyone wants to take up?

13 MS. PARKER: I had one small procedural matter, your  
14 Honor.

15 THE COURT: Ms. Parker, yes.

16 MS. PARKER: The parties today had met and conferred  
17 and submitted a joint proposed agenda. We took the liberty of  
18 doing that. Is that something that your Honor finds helpful?  
19 If so, we're certainly happy to continue doing that on an  
04:49PM 20 ongoing basis.

21 THE COURT: I looked at it, I found it helpful. It's  
22 not required. It's up to you. Again, I find when Judges  
23 require things, it just starts to add costs and complexity to  
24 things that aren't really necessary. I did find it helpful,  
25 but I don't need it all of the time, but I did look at it and I

1 did find it helpful.

2 MS. PARKER: Thank you.

3 THE COURT: Anyone on the telephone want to raise  
4 anything? Hearing nothing, thank you, we will stand in recess  
5 and have a good holiday. I'm sorry, I need to set the next  
6 date, don't I?

7 MR. FERN: Judge --

8 THE COURT: Yes, Mr. Fern.

9 MR. FERN: Judge, what I have found helpful in the  
04:50PM 10 past serving as liaison counsel in these other mass torts, and  
11 it may be a little bit too early to do that, but if the Court  
12 picks hypothetically the third Wednesday of every month so we  
13 can block that time on our schedules.

14 THE COURT: I expect to do that once we're up and  
15 rolling. It may not even be every 30 days, but I intend to do  
16 exactly that, but I'm not there yet. I don't know whether  
17 these cases are going to be mine or not, which is an important  
18 part of that.

19 MR. FERN: I understand.

04:50PM 20 THE COURT: I'm just trying to handle things in the  
21 interim.

22 MR. MORIARTY: I get back to Cleveland on the 3rd. I  
23 could be here by the 5th. I guess I could be here before it if  
24 we did it late in the day. I can send somebody in my place.

25 THE COURT: I have duty in Washington the week of the

1 7th. Let's put it down for the week of the 14th.

2 THE CLERK: You'll be in Worcester.

3 THE COURT: Maybe or maybe not. 2:00 on Monday,  
4 January the 14th.

5 MR. FERN: That will work, your Honor.

6 MS. PARKER: I will not be here, your Honor. I can  
7 send someone else, that will be fine.

8 THE COURT: Okay. It's going to be hard, is it just  
9 that day or that whole week?

04:52PM 10 MS. PARKER: It is the 11th through the 16th. If the  
11 4th is on the table, I hate to inconvenience Mr. Moriarty.

12 THE COURT: Well, there's no way I'm going to make all  
13 these pieces fit, and the 7th is not movable, the week of the  
14 7th is not movable for me. Again, it's a duty week for me in  
15 Washington, so I'm stuck with that. I think I'm going to have  
16 to stick with the 14th. Again, I understand that we're not  
17 always going to have every lead counsel available every time.  
18 We'll do the best we can.

19 Okay. All right. With that then, thank you and have  
04:52PM 20 a good holiday everyone, and I'll see you after the first of  
21 the year.

22 (Whereupon, the hearing was adjourned at 4:53 p.m.)

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## C E R T I F I C A T E

UNITED STATES DISTRICT COURT )  
DISTRICT OF MASSACHUSETTS ) ss.  
CITY OF BOSTON )

I do hereby certify that the foregoing transcript,  
Pages 1 through 32 inclusive, was recorded by me  
stenographically at the time and place aforesaid in Civil  
Action Nos. 12-12052-FDS and No. 12-12066-FDS, ERKAN, COLE, et  
al. vs. NEW ENGLAND COMPOUNDING PHARMACY, INC., d/b/a NEW  
ENGLAND COMPOUNDING CENTER, et al. and thereafter by me reduced  
to typewriting and is a true and accurate record of the  
proceedings.

Dated this 10th day of January, 2013.

s/s Valerie A. O'Hara

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VALERIE A. O'HARA

OFFICIAL COURT REPORTER